

Applicant	:	Peters et al.
Appl. No.	:	10/595,601
Examiner	:	Luther G. Behringer
Docket No.	:	13634.4011

REMARKS

The Office Action dated March 9, 2009 has been carefully considered. Claims 39—48 have been amended.

Claims 39—48 have been rejected as unpatentable over Kapp et al. Patent No. 4,256,094 in view of Krueger Patent No. 3,552,383. The examiner has asserted that Kapp discloses a "heart assist device". This is an incorrect. Kapp is directed to a device for reducing the arterial blood pressure to a selected body site such as the head or brain by occluding or partially occluding the artery using an inflatable cuff.

The present invention is not directed to a device for reducing downstream blood pressure. Rather, it is directed to the control of an aortic pulsatile heart assist device. The two types of devices are fundamentally different. A heart assist device is a device that assists the heart to pump blood around the body and the Kapp device has no role in doing that. Kapp discloses a device that uses an inflatable cuff to constrict the flow of blood from the heart to a peripheral organ in order to reduce the blood pressure in that organ. A patient requiring arterial blood pressure reduction therapy will not need pumping assistance of the type described in the present application. Conversely, a patient who needs heart assist therapy of the type described in the present application will not need arterial blood pressure reduction therapy.

There is absolutely no disclosure in Kapp involving pulsatile heart assist of the aorta nor is there any disclosure in Kapp of any device for controlling a pulsatile heart assist device which is coupled to a blood vessel. The claims are cast as Jepson type claims such that the preamble of these claims must be taken into account as a meaningful element of the claims. The effect of Jepson type claims is explained in some detail in Rowe v. Dror, 112 F.3d 473, 479 (Fed. Cir.

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1997) and in *Manual of Patent Examining Procedure*, Section 608.01m. As stated in the latter, the Jepson form of claim:

“is to be considered a combination claim. The preamble of this form of claim is considered to positively and clearly include all the elements or steps recited therein as part of the claimed combination.”

Thus, it is believed that the rejection based on Kapp is not applicable as Kapp does not disclose, teach or suggest a heart assist device or a apparatus for controlling the pulsations of a heart assist device.

Krueger is relied upon for its disclosure of a microphone for sensing Korotkoff sounds. This disclosure in Krueger does nothing to remedy the deficiencies in Kapp pointed out above.

Furthermore, Krueger relates to diagnostic technology that is quite different from the technology for assisting the heart to pump blood around the body. Krueger is a system for a automated estimation of arterial blood pressure using a pressure cuff and a microphone to monitor Korotkoff sounds. Korotkoff sounds are "The noises heard when taking a blood pressure reading, originated by blood passage causing vibrations in the walls of the blood vessel" (Google definitions). They are thus blood vessel wall noises NOT heart sounds. (Wikipedia ("The sounds heard during measurement of blood pressure are not the same as the heart sounds 'lub' and 'dub' that are due to the closing of the hearts valves."))

Neither Kapp or Krueger has any direct relevance to the claimed invention. Neither of these references relate to a heart assist device, nor do they make any use of heart sounds for any purpose. Most importantly neither of them, alone or taken together, suggests that there is any advantage in placing a microphone within a fluid positioned to transmit pressure between a pump and a balloon on a heart assist device.

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Thus, the Examiner's suggestion regarding modifying Kapp to include the microphone of Krueger has no basis. The teachings of Kapp and Krueger would not be combined by a person skilled in the art as suggested by the examiner for a number of reasons. Firstly Kapp and Krueger relate to quite different medical arts, on the one hand restricting blood pressure in an organ (Kapp) and on the other hand measuring a patients general blood pressure using an automated blood pressure cuff of the type commonly used by physicians (Krueger). Secondly there is absolute no reason to modify Kapp with an external microphone to monitor Korotkoff sounds to estimate arterial pressure since Kapp already measures actual arterial pressure using a pressure sensor coupled directly to the artery. Thirdly even if such an arrangement were envisaged by a physician it would not be a "heart assist device" or have any relevance to such a device. Fourthly even if such a device were envisaged by a physician there is no suggestion of teaching that the microphone should be positioned in the liquid between the pump and the cuff or balloon. In the case of the Kapp device the sensor (in that case a pressure sensor) is placed on the exterior of the blood vessel NOT in the fluid connecting the pump to the cuff. If there were any point in combining Kapp and Krueger (which Applicants submit there is not) then the simple course of action would be to place Krueger's microphone where Kapp had his pressure sensor.

Applicants submit that the examiner has used the teaching of the Applicant's application to come up with the postulation that a person combining Kapp and Krueger would put Krueger's microphone into the liquid pressure supply of Kapp. There is no suggestion of that whatsoever in the art cited by the examiner. Moreover, the Examiner taking of Official Notice of sound waves travel faster in an incompressible media versus a compressible one is of no relevance as Kapp notes the pump is connected to a suitable fluid reservoir. (Col 3, lines 17—19). One skilled in

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the are would readily understand "fluid" to comprise both compressible and incompressible fluids such as a liquid and a gas. What the examiner has done is to draw that idea from the Applicant's application and added that knowledge to the teachings of Kapp and Krueger. It is therefore believed that the Examiner has gone farther than the law permits in looking for elements recited in claims 39—48 in different prior art references and then attempting to put them together in an impermissible attempted reconstruction of Applicant's invention.

The attempt to combine the pressure reduction of Kapp with the blood pressure estimation of Krueger appears to be entirely based on the disclosure in Applicant's specification. The statement by the Examiner that it would have been obvious to a person of ordinary skill to add an external microphone to Kapp just because Krueger using a microphone in conjunction with an occluding arm cuff is entirely baseless. Since Krueger is directed to sensing, actually estimating, pressure, the combination of Kapp and Krueger would replace the pressure sensor of Kapp with the microphone or the microphone and cuff of Krueger to estimate the arterial pressure downstream of the Kapp's occluding cuff. If the pressure sensor is replaced with only the microphone then the pressure in Kapp's cuff would need to be modified while the Korotkoff sounds are monitored by the microphone. The pressure in Kapp's cuff would then need to be subsequently modified to constrict the blood flow. Alternatively, Kapp's pressure sensor would be replaced by Krueger's cuff and microphone to estimate instead of measure pressure. As a result, the combination of Krueger with Kapp makes no sense and would simply distort Kapp's technology. Neither Kapp nor Krueger has any pertinence to control of a pulsatile heart assist device. The lengths to which the Examiner has gone in an effort to reconstruct the claimed invention go well beyond what is permitted by the law. Claims 39—48 are believed to be

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patentable. Thus, it is respectfully requested that the rejections based on Kapp and Krueger be withdrawn.

It is believed that the present application is in condition for allowance and a favorable action is respectfully solicited.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 15-0665.

Respectfully submitted,
ORRICK, HERRINGTON & SUTCLIFFE LLP

/Kenneth S. Roberts/

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By: _____
Kenneth S. Roberts, Reg. No. 38,283

Orrick, Herrington & Sutcliffe LLP
4 Park Plaza, Suite 1600
Irvine, CA 92614-2558
Tel. 949-567-6700
Fax: 949-567-6710